

## **REMARKS**

### Rejection of Claims 1-5, 8-14, 16-17, 29-30, 35-39, and 41-42 Under 35 U.S.C. § 103

Claims 1-5, 8-14, 16-17, 29-30, 35-39, and 41-42 stand rejected under 35 U.S.C. § 103 as being anticipated by Malone (U.S. Patent No. 6,110,898) in view of O'Hagan (U.S. Patent No. 6,534,064).

The Office Action at page 5 concedes that "Malone *et al.* does not teach the administration of a detoxified bacterial ADP-ribosylating toxin, which are adjuvants." The Office Action cites O'Hagan as remedying this omission. In particular, the Office at page 6 cites O'Hagan as teaching LT-K63, LT-R72, CT-S109, PT-K9/G129 and CpG oligonucleotides. Applicants respectfully traverse the rejection.

O'Hagan is not available as prior art to the present application. Applicants assume that the Patent Office considered O'Hagan prior art under § 102(e). A reference is disqualified under 35 U.S.C. § 103(c) when subject matter which would otherwise be prior art to the claimed invention and the claimed invention are commonly owned or subject to an obligation of assignment to a same person at the time the claimed invention was made. 35 U.S.C. § 103(c).

Applicants state herein that O'Hagan and the current invention were commonly owned or subject to an obligation of assignment to Chiron Corporation at the time the invention was made, as shown on the face of the patent.

Applicants therefore request disqualification of O'Hagan as prior art.<sup>1</sup>

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<sup>1</sup> Applicants note that WO 01/26681 (disclosed in the accompanying IDS) is related to O'Hagan. WO 01/26681 was published on April 19, 2001. WO 01/26681 is not prior art under § 102(a) with respect to the detoxified bacterial ADP-ribosylating toxins, however, as the instant application claims priority to US provisional application No. 60,261,554, filed January 12, 2001, which pre-dates WO 01/26681 and contains support for the detoxified bacterial ADP-ribosylating toxins.

In the absence of O'Hagan's teachings, the Patent Office's assertion of obviousness cannot stand. To establish a *prima facie* case of obviousness, the prior art references should teach or suggest all the claim limitations. Claim 1 recites a detoxified bacterial ADP-ribosylating toxin. As the Office Action concedes, Malone *et al.* does not teach the administration of a detoxified bacterial ADP-ribosylating toxin. Therefore, the Patent Office has failed to create a *prima facie* case of obviousness. The remaining claims depend from claim 1 and are allowable for the same reason.

Applicants respectfully request withdrawal of the rejection.

#### Rejection of Claim 15 Under 35 U.S.C. § 103

Claim 15 stands rejected as obvious based on Malone *et al.* in view of O'Hagan *et al.* The Office states at page 7 that neither reference "teaches the invention encompassed by claim 15." However, the Office Action contends that in view of the combined teachings of O'Hagan and Malone it would have been obvious to modify "the gene delivery vehicle of Malone *et al.* to include a second alphavirus construct," *Id.*, and that the skilled artisan "would have been motivated to do so to determine a workable or optimal gene delivery vehicle." *Id.*

Applicants respectfully traverse the rejection.

As noted above, O'Hagan is not prior art to the current invention and therefore this rejection fails for the same reason advanced above.

Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

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